UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/507,127	09/10/2004	Keiichi Abe	47233-0044	8837

55694 7590 04/17/2008

DRINKER BIDDLE & REATH (DC)
1500 K STREET, N.W.
SUITE 1100
WASHINGTON, DC 20005-1209

EXAMINER	
TRAN LIEN, THUY	

ART UNIT	PAPER NUMBER
1794	

MAIL DATE	DELIVERY MODE
04/17/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/507,127	ABE ET AL.	
	Examiner	Art Unit	
	Lien T. Tran	1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 January 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,8-11 and 20-35* is/are pending in the application.

4a) Of the above claim(s) *33-35* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,8-11 and 20-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/8/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Newly submitted claims 33-35 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claims 33-35 are distinct species from the originally claims because they are directed at pharmaceutical composition comprising an SDS-rich product while the original claims are directed to food and/or drink product. Pharmaceutical composition is different from food product.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 33-35 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim1-5,25-27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In the response filed 1/4/08, applicant amends claim 1 to include the limitation of " washing the column with 0-10% alcohol"; the specification does not disclose this step. Example 4 pointed by applicant only discloses washing with water. Also, there is no disclosure of the range 15-40%. Example 4 discloses 10%, 15%, 20% and 40%; however, the range claimed contains value not disclosed in the set. For example, there is no disclosure of 25,30% etc.. There is no disclosure of washing with ethanol as recited in claim 26.

Claims 6,28-32 are rejected under 35 U.S.C. 102(e) as being anticipated by Pihlava et al (WO 02/062812A1).

Pihlava et al disclose a process for preparing an SDG-rich food comprising the step of extracting a plant material containing SDG with a basic alcohol such as ethanol or methanol. The plant material is defatted flaxseed. The basic alcohol is sodium hydroxide-methanol. (page 2, lines 21-28, page 3 lines 25-31. Pihlava et al disclose a process comprising the step claimed.

Pihlave et al disclose an SDG-rich product obtained by extracting with basic alcohol. The limitations on alcohol concentration and extraction temperature are differences in processing parameters which do not determine the patentability of the product-by-process claims. Claim 29 further defines the flaxseed residue but the claim does not positively claim the flaxseed residue because claim 28 recites the alternative of flaxseed or flaxseed residue. Furthermore, such difference is in processing which does not determine the patentability of the product

Claims 1-5,25-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pihlava et al

Pihlava et al disclose a process for preparing an SDG-rich food comprising the step of extracting a plant material containing SDG with a basic alcohol. The plant material is defatted flaxseed. The basic alcohol is sodium hydroxide-methanol. The SDG can be enriched by chromatography. For instance, a mixture having the SDG mixed with c18 material is packed in a flash chromatography system. The column is finally equilibrated with water-methanol or water-ethanol used as the eluant. SDG is

eluted from the sample cartridge with a water-methanol or water-ethanol mixture. The column is washed with methanol-water or ethanol-water. The sample-c18 mixture can also be packed into an open c18-chromatography column and SDG can be correspondingly eluted therefrom with methanol or ethanol. The flaxseed is ground to a particular powder. The example on page 6 lines 29-30 discloses that SDG is eluted with 650ml of 40% methanol. (page 2, lines 21-28, page 3 lines 25-31, page 4 lines 20-30 and the example)

Pihlava et al do not disclose the concentration of alcohol as in claims 4,25, the temperature as in claims 27, and washing with the alcohol concentration as in claim 1.

Pihlava et al teach enriching for SDG on the column; thus, Pihlava et al teach applying the extracted solution to a resin column. Pihlava et al teach washing with water and water-alcohol solution; it would have been obvious to one skilled in the to determine the appropriate alcohol concentration to obtain the most optimum product. The concentration used is a result-effective variable which can readily be determined through routine experimentation. It would have been within the skill of one in the art to determine the appropriate concentration of alcohol to obtain the most optimum extraction. The amount is a result-effective variable which can readily be determined by one skilled in the art through routine experimentation. It would also have been obvious to one skilled in the art to determine the appropriate temperature through routine experimentation to obtain the most optimum extraction. Applicant has not shown criticality or unexpected result with respect to the temperature.

Claims 8-11, 20-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pihlava et al in view of Empie et al.

Pihlava et al do not disclose adding the SDG-rich product to material for food and/or drink, the amount of daily intake of SDG, the amount of SDG in the food and the health benefits as claimed.

Empie et al disclose a composition comprising SDG and isoflavones. The composition is made in the form of pill, tablet, capsule, liquid or ingredient in a food including health bars. The composition has health benefits such as alleviating hot flahes, osteoporosis, symptoms associated with menstruation and other health benefits. The composition may also be administered as a food supplement or as a food ingredient. (see col. 3 lines 34-55, col. 6 lines 57-67, col. 7 lines 17-21)

It would have been obvious to one skilled in the art to add the SDG-rich product of Pihlava et al to food and drink to obtain the health benefits shown by Empie et al. It would have been obvious to add the SDG to any food product or drink when it is desired to obtain the health benefits provide by SDG in such food or drink product. It would have been obvious to add the SDG in any amount to obtain any varying daily intake depending on the benefits desired. Such parameter can readily be determined by one skilled in the art through routine experimentation.

In the response filed 1/4/08 applicant comments that the claims as amended require a different set of steps than the steps taught by Pihlava. The amended claims do not define over Pihlava as set forth in the rejection above. It is not clear what applicant means by fewer steps; in any event, the claims do not exclude additional

steps. Applicant comments the process described by Pihlava is not capable of producing a product with such a high content of amino acid. It is not clear what amino acid content applicant is referring to. There is no limitation of amino acid content in the claims.

Applicant also argues that there must be some sort of teaching or motivation to vary the amount of a variable. This argument is not persuasive. The examiner maintains her position that the concentration of alcohol used in a result-effective variable which can be determined through routine experimentation to obtain the most optimum extraction. A 103 rejection must take into consideration the skill of one in the art. In doing the extraction, it is inherent that a certain concentration of alcohol is used. If after a run, it is determined that the concentration of alcohol used does not give the most desirable extraction, it would have been readily apparent to one skilled in the art to experiment with various concentrations to obtain the most optimum extraction. The experiment is not undue and would have been within the skill of one in the art. Applicant has not shown any unexpected result or criticality with respect to the amount claimed. In fact the amount claimed is a conventional amount used for extracting SDG as shown in Jp9-208461 in the IDS submitted with the amendment. Applicant traverses the rejection of claims 8-11, 20-24 with respect to claim 6. The traversal is not persuasive as Pihlava et al do disclose the SDG-rich product as claimed.

The changes in the rejections are necessitated by amendment.

Applicant's arguments filed 1/4/08 have been fully considered but they are not persuasive.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lien T. Tran whose telephone number is 571-272-1408. The examiner can normally be reached on Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Milton Cano can be reached on 571-272-1398. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Monday, April 14, 2008

/Lien T Tran/

Primary Examiner, Art Unit 1794

***